

**REMARKS**

In the Office Action mailed October 16, 2003, the Examiner rejected Claims 1-7, 9-16 and 79-86 under 35 U.S.C. § 103(a) as being obvious in view of U.S. Patent No. 3,823,818 to Shaw. Further, Claims 17-19 and 91-106 were rejected under 35 U.S.C. § 103(a) as being obvious over Shaw in view of U.S. Patent No. 5,884,457 to Ortiz et al., and Claims 87 and 88 were rejected under 35 U.S.C. § 103(a) as being obvious over Shaw in view of U.S. Patent No. 5,651,775 to Walker et al. Applicant submits that all pending claims are allowable over the art.

In particular, independent Claims 1, 92 and 102 are each directed to an apparatus adapted for automated handling and comprising a plurality of syringe bodies, each syringe body including a barrel having a dispensing end and an opposing end, a plunger slidably disposed in the opposing end, and a cap removably disposed on the dispensing end, wherein a clean, contained volume is defined within the barrel. The apparatus further includes a flexible belt fixedly attached to the barrels of each of the plurality of syringe bodies, wherein the syringe bodies are positionable in a predetermined orientation with at least one of the ends of each barrel being accessible. Such an arrangement facilitates automated handling processes for a plurality of syringe bodies while also facilitating the efficient provision and maintenance of a clean, contained volume in each of the syringe bodies in conjunction with the automated handling. As may be appreciated, the efficient provision and maintenance of a clean, contained volume within syringe bodies is of importance in the field of products for fluid medication administration.

In contrast to the invention of Claims 1, 92 and 102, Shaw is directed to thermoplastic container blow molding (e.g. bottles) utilizing unfinished, open-ended preforms and fails to disclose or suggest an apparatus comprising a plurality of capped, syringed bodies having clean, contained volumes that are interconnected by a flexible belt. Further, Shaw fails to disclose or suggest any applicability of the teachings thereof to the field of medical products, including products for fluid medication administration. Concomitantly, Shaw fails to address or even recognize the desirability of an apparatus that facilitates the efficient provision and maintenance of a clean, contained volume. Indeed, since the unfinished preforms of Shaw are open-ended, Shaw's teachings are not capable of

facilitating the provision and maintenance of a clean, contained volume in automated handling or otherwise.

In view of the foregoing, Applicant submits that the invention of Claims 1, 92 and 102 is not obvious in view of Shaw. In further support of such position, Applicant is submitting herewith a Declaration Under 37 C.F.R. § 1.132 of Randall W. Smith. Further, Applicant is submitting herewith a secondary consideration Declaration in Support of Non-Obviousness by Jeffrey V. Baldwin.

Applicant submits that Ortiz et al. also fails to disclose or suggest the invention of Claims 1, 92 and 102, i.e. an apparatus having a plurality of syringe bodies and a flexible belt fixedly attached to the barrel of each of the syringe bodies. Rather, Ortiz is directed to a method and apparatus in which non-interconnected delivery devices 12 are filled by individual positioning of the non-interconnected delivery devices 12 in a non-flexible feeding magazine 26 disposed on a non-flexible frame 24 of a filling machine 10 for movement along a pre-determined path of the filling machine 10. See, Column 6, Lines 10-17; Column 6, Lines 27-40 with Fig. 6; Column 7, Lines 6-12; and Column 7, Lines 21-27. In this regard, it is important to note that the only apparatus for handling delivery devices 12 that is described by Ortiz et al. is the feeding magazine 26 within which delivery devices 12 are separately, supportably and removably positioned. In order to provide such functionality, the feeding magazine 26 is not flexible and is not fixedly attached to any portion of the delivery devices 12.

In addition to the respective shortcomings of Shaw and Ortiz et al., Applicant submits that such references are not combinable to render obvious the invention of Claims 1, 92 and 102. In this regard, and as noted above, Shaw fails to disclose or suggest any applicability of the teachings thereof to the field of medical products, including products for fluid medication administration (e.g. syringe bodies). Further, Shaw fails to address or recognize the desirability of providing and maintaining a clean, contained volume in an apparatus, and otherwise fails to disclose any apparatus for doing so. Rather, Shaw actually teaches away from such an apparatus by providing open-ended, unfinished preforms. Further in this regard, Shaw notes that when the open-ended, unfinished preforms are to be blow molded into containers:

“[T]he individual preforms are . . . fed rapidly into a heating device, such as the heating and blowing tables disclosed in U.S. Pat No. 3,599,280. In these units, the preform is heated sufficiently to enable it to be blow molded into the final container or bottle configuration.” Column 4, Lines 22-28.

Applicant notes that a review of the referenced U.S. Patent No. 3,599,280 reveals that the various machine embodiments disclosed /described therein contemplate operation upon open-ended, unfinished preforms, and make no provision for and appear to be inoperable for handling preforms or any other vessel that is capped with a clean, contained volume. A copy of U.S. Patent No. 3,599,280 is provided herewith for the Examiner convenience.

In view of the foregoing, Applicant submits that Shaw fails to provide any suggestion or motivation to combine the teachings thereof with Ortiz et al., much less in a manner that would yield the invention of Claims 1, 92 and 102. In fact, given the open-ended, unfinished nature of the preforms taught by Shaw, Applicant submits that Shaw actually teaches away from the apparatus of Claims 1, 92 and 102.

Further, Applicant submits that Ortiz et al. fails to provide any suggestion or motivation to combine the teachings thereof with Shaw, much less in a manner that would yield the invention of Claims 1, 92 and 102. In this regard, Applicant again notes that in Ortiz et al. non-interconnected delivery devices 12 are filled by individual and separate positioning in a non-flexible feeding magazine 26 of a filling machine 10 for movement along a predetermined feeding path of the filling machine 10. As shown in Figs. 6 and 7, and described at Column 6, Lines 27-51 of Ortiz et al. the feeding magazine 26 includes a guide flange 32 with separate apertures 34, each aperture 34 being provided to receive an end of a single, separate delivery device 12 that is inserted therein. Further, the feeding magazine 26 includes a support flange 36 with separate notches 38, each notch 38 having grooves 42 for receiving linear portions 40 of a single, separate delivery device 12. Applicant submits that such an arrangement fails to provide any suggestion or motivation for, and actually teaches away from a modified arrangement in which the delivery devices 12 are interconnected in any manner, much less utilizing any features of Shaw. Indeed, in view of the purpose and design of the feeding magazine 26, there would be no purpose or need for such a combination. Moreover, the

arrangement of Shaw would not appear to be workable in the Shaw filling machine 10 either in combination with or in place of feeding magazine 26.

In further support of the non-obviousness of Claims 1, 92 and 102 over Shaw and Ortiz et al., Applicant again notes the Declaration Under 37 C.F.R. 1.132 of Randall W. Smith submitted herewith. Further, Applicant again notes the Declaration in Support of Non-Obviousness by Jeffrey V. Baldwin submitted herewith.

With further particular respect to independent Claims 92 and 102, Applicant notes that the apparatus defined thereby further stipulates that the caps disposed on each of the syringe bodies are both removable from and replaceable upon the dispensing ends thereof. Additionally, Claim 92 provides that the flexible belt interconnecting the plurality of syringe bodies is of a predetermined length between adjacent ones of the syringe bodies, wherein said predetermined length is sufficient to define label flaps upon severance of the belt between adjacent ones of the syringe bodies, and wherein at least one surface of each predetermined length of the belt is adapted for printing contents-related information thereon. Applicant submits that, the inclusion of the noted features provides further basis for the allowability of independent Claims 92 and 102.

For example, with respect to Claim 92, Shaw and Ortiz et al. fail to provide any disclosure as to the provision of label flaps or surfaces adapted for printing contents-related information thereupon. In fact, Shaw actually teaches away from such features stating:

“When it is desired to produce containers using the belted preforms, it is a simple matter to remove a loaded reel from its storage and shipping container **60** and feed the outer end of the preform web to a suitable stripping device whereby with the application of a suitable solvent, heat, or by the use of a severing mechanism, the individual preforms are sequentially separated from the plastic web and fed rapidly into a heating device . . .”. Column 4, Lines 16-25.

The noted stripping of the plastic web and heating of the separated preforms is inconsistent with the provision of the features of Claim 92 noted above.

For the record, Applicant notes that it is clear that the prior art must teach or otherwise motivate a combination of prior art references. For example, in the CAFC decision of *In re Anita*

*Dembiczak and Vincent Zinbarg*, 175 F.3d 994, U.S.P.Q.2D (BNA) 1614 (Fed. Cir. 1999) the Court stated:

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2D (BNA) 1225, 1232 (Fed. Cir. 1998) (describing “teaching or suggestion or motivation [to combine]” as an “essential evidentiary component of an obviousness holding”); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2D (BNA) 1453, 1459 (Fed. Cir. 1998) (“the Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”); *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2D (BNA) 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination “only by showing some objective teaching [leading to the combination]”); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2D (BNA) 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion “essential” to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 U.S.P.Q. (BNA) 657, 667 (Fed. Cir. 1985) (district court’s conclusion of obviousness was error when it “did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination”). See also *Graham*, 383 U.S. at 18, 148 U.S.P.Q. (BNA) at 467 (“strict observance” of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 U.S.P.Q. (BNA) 543, 547 (Fed. Cir. 1985) (“The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.”). In this case the Board fell into the hindsight trap.

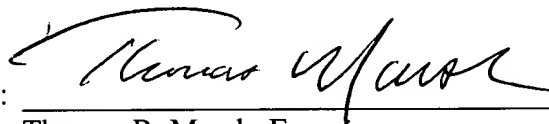
Applicant submits that in the present case the Examiner’s combination of Shaw and Ortiz et al. is the result of inappropriate hindsight analysis and, for the various reasons noted above, Applicant respectfully requests withdrawal of claim rejections based thereupon.

In view of the foregoing, Applicant believes that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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2/17/04